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Biotechnology

Annual

2007

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Report Highlights:

Paraguay is the fourth largest soybean exporter in the world, producing about two percent of the world's soybean production. The country increased its biotech soybean area another 10 percent in 2006, to account for 90 percent of the country's total soybean crop. There are ten soybean Round Up Ready (RR) varieties approved for planting and commercialization; and Bt cotton (Monsanto variety) has been approved for experimentation.

The royalties collection system agreed between Monsanto and farmers continues to operate. The GOP is informed once the price is set.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Buenos Aires [AR1]
[PA]

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I. Executive Summary

Paraguay is the fourth largest soybean exporter in the world, producing about two percent of the world's soybean production. The country increased its biotech soybean area another 10 percent in 2006, to account for 90 percent of the country's total soybean crop. Up until the 2004/2005 season, the country did not allow the use of biotech seeds.

Paraguayan farmers agreed in March 2005 to pay royalties to Monsanto for the use of its GMO soybeans starting the 2004/2005 crop year. Since then, Monsanto and the farmers have agreed upon the price based on each year's production campaign.

This crop season controversy arose once again over biotechnology. Paraguayan farmers are very receptive to anti biotech propaganda from the media and NGOs that has focused on cotton which is mainly produced by small farmers.

Paraguay is still working to pass and implement a biosafety law. Since 2003, the Paraguayan National Congress has been evaluating a draft biosafety bill that would regulate the eventual production and commercial release of GMO products in Paraguay. The Ministry of Agriculture drafted the bill collaboratively with FAO, and with input from interested sectors of the Paraguayan society. As the bill is written, the Ministries of Agriculture, Environment and Health will jointly enforce the law, while the Biosecurity Commission, which was created in 1997, will continue to advise the Ministries on technical issues. The National Service of Seed and Vegetables Quality, (SENAVE) would advise the Ministry of Agriculture on policy issues. As of today, there are no updates from the Congress regarding the biosafety bill.

In 2003, Paraguay ratified the Cartagena Biosafety Protocol (CBP). The Secretariat of Environment is seeking Paraguayan Central Government consent to administer the provisions of the CBP. However, this request has met with resistance from other ministries, as there is concern that the Secretariat of Environment does not have the technical expertise required.

II. Biotechnology Trade and Production

Paraguay approved in October 2004 four soybean varieties containing Roundup Ready (RR) genes, for planting and marketing. About 90 percent, or 2.6 million hectares of total soybean area, is planted with RR varieties for the current crop season. At the moment there are ten soybean RR varieties approved for planting and commercialization. Bt cotton (Monsanto variety) has been approved for experimentation. (Appendix A)

There are three corn varieties under analysis, MON 810, NK 603, and BTRR (MON 810 x NK603) as well as two cotton varieties: RR and BtRR (both Monsanto varieties).

Paraguay imports biotech seeds from Argentina (nearly 80 %) and from Brazil.

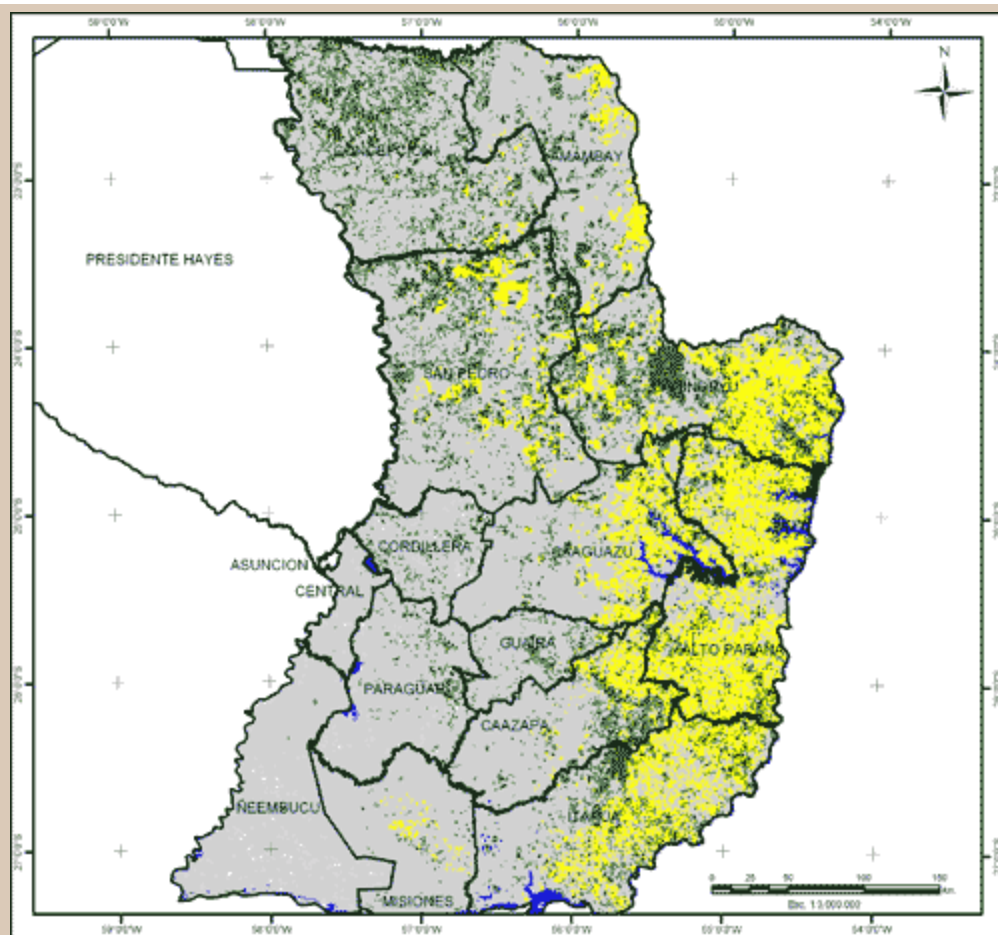
Approvals in Argentina, the United States, and Canada are taken into account as a precedent in the approval evaluation process.

Soybeans Area and Production






YEAR	PRODUCTION (Metric Tons)	AREA (Hectares)	YIELD (Kgs/Ha)
1996	2.408.428	960.000	2.509
1997	2.771.000	1.050.000	2.639
1998	2.988.201	1.150.000	2.598
1999	2.980.058	1.200.000	2.483
2000	2.911.423	1.200.000	2.426
2001	3.502.179	1.350.000	2.594
2002	3.546.674	1.445.000	2.454
2003	4.518.015	1.550.000	2.915
2004	3.911.415	1.936.600	2.020
2005	4.040.828	2.000.000	2.020
2006	3.641.186	2.426.000	1.501
2007 (est)	6.200.000	2.630.000	2.700

Source: CAPECO (2007)

Satellite Study Soybeans Area (2007)



Región Oriental del Paraguay

Reference		DEPARTAMENTOS	Area(has.)	%
	Soybean	01 - CONCEPCION	18.383	1
	Forest	02 - SAN PEDRO	156.120	6
	Others	04 - GUAIRA	9.646	0
	Water	05 - CAAGUAZU	253.747	10
	Departments	06 - CAAZAPA	126.758	5
		07 - ITAPUA	559.528	23
		08 - MISIONES	19.599	1
		10 - ALTO PARANA	732.973	30
		13 - AMAMBAY	110.279	5

	14 - CANINDEYU	442.763	18
	Source: CAPECO		

III. Policy

Current Situation of Regulatory Framework

The current regulatory framework applied to biotech seeds and to biosecurity is incomplete. Paraguay, in recognition of its need to regulate biotech seeds, proposed a biosecurity law based on discussions within the biosecurity commission, regulations in place in MERCOSUR countries and the results of three public hearings.

The Paraguayan Congress has been evaluating this proposal since April 2003.

As a party to the Convention on Biological Diversity, and signatory of the Cartagena Biosafety Protocol, Paraguay was eligible to receive funding from the United Nations Environment Programme to develop a "National Biosafety Framework". The project started in 2005 and concluded in July 2007. Although it was an interdisciplinary task, the Secretariat of the Environment (SEAM) was mainly in charge of the project.

Laws or regulations currently in force regulate approval for experimentation and commercialization of biotech seed. These laws and/or regulations are related to compliance with international laws, such as article 19 of the Cartagena Protocol, and national laws and regulations that protect the environment, biodiversity, and human health. In 1997, under Decree 18481, the Biosecurity Commission was created, with the objective of analyzing and advising on the introduction, field trials, and environmental release of biotech plants. This commission acts as an advisory organism and includes representatives of the Ministry of Health, the Ministry of Agriculture and Livestock and the Ministry of Environment, as well as representatives of scientific institutions and representatives of the production sector.

Functions of this commission include the receipt and evaluation of requests for use of GMOs, as well as:

- risk analysis, (a private company selected by public competition will carry out this analysis),
- as requested by the involved ministries, the Commission will cooperate with the functions of control and inspection.
- information exchange with national and/or international public and private institutions in reference to risk analysis and approval for commercialization of GMOs.
- will provide technical advice to the involved ministries in reference to policy implementation and national strategy related to biosecurity.

Creation of SENAVE

In October 2004, under Decree 5042, a new organism was created-- the National Service of Plant Health Quality, SENAVE (Servicio Nacional de Calidad y Sanidad Vegetal, in Spanish)-- as a merger of the National Seed Direction, the National Direction of Plant Protection, the National Control Office for Tobacco and Cotton and the Office in charge of domestic and international commercialization of vegetable sub products of the Ministry of Agriculture.

In general terms, the functions of SENAVE are to:

- Prevent the introduction of exotic diseases in the country.
- Lead on issues related to Biotechnology.
- Enforce all established laws related to seed and cultivar protection.

- Enforce international agreements related to seed quality and safety and to protect vegetal biotech species.
- Advise the Minister of Agriculture in formulation and continuation of a national policy related to production of seed and products derived of biotechnology.

Traceability

No provision for a traceability system is in place nor has this been included under the proposed law. Tests for biotech content on shipments arriving in Paraguay are not contemplated either.

Labeling

Biotech products that are marketed in the future may be required to bear a label that contains specific information required by the Ministry of Industry and Commerce. It should be noted that officials of the Ministry of Agriculture, when questioned about labeling requirements, responded that Paraguay would establish information requirements for labeling according to CODEX resolutions. However, this is not stated in the proposed law, where provisions for labeling are vague.

Stacked Genes

Paraguay has not yet established a policy on stacked genes.

Coexistence

Paraguay has not yet established a policy on coexistence.

Royalties

Framework Agreement signed in support of Royalty Collection System

Paraguayan farmers agreed on March 2, 2005 to pay royalties to Monsanto Co. for its biotech soybeans beginning in the 2004/2005-crop year. Paraguayan farmers, as well as those in Brazil and Argentina, had used Roundup Ready soybean seeds for years without paying royalties. For the current campaign, they will pay \$3.09 per bag of seed used to sow one hectare, in consideration to the yields of the last campaign, which is an increase compared to the \$2.60 paid in the previous campaign. The price is negotiated between the provider of the technology (in this case Monsanto) and the user (the farmer), informing the GOP once the price is set. The agreement was signed between Paraguayan farm lobby groups and Monsanto's Paraguayan branch, and a portion of those royalties will go to crop research and germoplasm improvement within the country.

The system used to remunerate inventors for their technology is similar in structure to the grain-based program implemented in southern Brazil last year. A commission that included members of grower associations, grain handlers, technology providers, and seed companies designed this system.

As part of its commitment to Paraguayan agriculture, Monsanto plans to fund research and development projects agreed to by the government and agricultural providers that analyze different technologies and germplasm across a range of growing regions throughout the country. At this point, the Institute for the Incorporation of Biotechnology (INBIO), underwent and finalized all the legal procedures, and has received the first payment (10% of

received royalties) that Monsanto provided as stipulated in the March 2005 agreement. The INBIO, an organization that integrates representatives of the whole Paraguayan agricultural sector, is in charge of financing training and research related to Biotechnology. Investment percentages are used as follows: 55% research; 15% grants; and 30% to strengthen the sector.

Although this royalties collection scheme is only negotiated for soybeans (eventually it will be negotiated for cotton and corn once approvals are granted), is a positive step in closing Latin America's biotech black market. It is based on grain production collected at delivery points. A portion of the fees collected will go to crop research and germoplasm improvement in Paraguay.

IV. Marketing Issues

Since Brazil is a major destination for Paraguayan soybeans; Paraguay's approval policy for GMOs is closely linked to Brazilian policy. Additionally, it is important to mention that the Paraguayan public is not well educated on the topic of agricultural biotechnology. Limited knowledge of popular science among consumers has led to many myths and rumors regarding agricultural biotechnology. The situation of misinformation is even worse in rural areas, where some NGOs put pressure on small farmers against the adoption of agricultural biotechnology.

There are no relevant studies on marketing of biotechnology products in Paraguay.

V. Capacity Building and Outreach

2002

- A. FAS Buenos Aires organized a Biotechnology seminar in Paraguay that was very successful in term of attendance (over 400 participants)
- B. Through Cochran Funds, FAS Buenos Aires sponsored a two-week biotechnology training in the United States for two Paraguayan government officials, organized collaboratively by FAS' Office of Capacity Building and Development (OCBD) and Michigan State University

2004

- A. FAS Buenos Aires selected one Paraguayan journalist that participated in a US Grains Council activity in Hawaii, where they learned about the Papaya industry.
- B. Through Cochran funds, FAS Buenos Aires sponsored a two-week biotechnology training in the United States for one representative of the Paraguayan government, organized by OCBD and Michigan State University.
- C. FAS Buenos Aires selected two Paraguayan producers that attended the Farmer-to-Farmer workshop at the University of Zamorano, Honduras.

- D. FAS Buenos Aires organized a two-day conference directed to Paraguayan Congressmen, but also to media, academia, government officials, and public in general, as a continuation of the seminar organized in 2002. The activity was very successful in terms of attendance (48 congressmen attended the first day and 300 people attended the second day).

2005

- A. FAS Buenos Aires in concert with FAS Santiago and OCBP organized and accompanied a Southern Cone Congressional Delegation to the United States, to demonstrate how the United States uses and regulates agricultural biotechnology. One Paraguayan Deputy participated in the activity.

2007

FAS Buenos Aires in concert with the US Codex office organized a working meeting where representatives of several Latin America and Caribbean Countries, including Canada and the US, discussed their countries' positions regarding labeling of Biotech foods.

Proposed activities

FAS Buenos Aires proposes a continuation of education and outreach activities as well as a more targeted information campaign. Specific activities may include:

- A. Workshops in different cities to target producers and consumers around the country, in areas that rarely have access to "first hand" information.\
- B. Coordination with local universities to demonstrate the benefits of biotechnology in Paraguay.
- C. Continue Cooperator, Cochran and International Visitor Program activities
- D. Conduct special activities designed for Consumer Association leaders and consumers in general.
- E. Workshop specifically targeting medical doctors and nutritionists, explaining the innocuousness of biotech products.
- F. New strategies along with more frequent and sustained efforts to better educate small farmers to understand biotechnology.
- G. Conduct a regional workshop in risk assessment directed to Argentine, Paraguayan, and Uruguayan experts.
- H. Organize a seminar especially directed to journalists.
- I. Organize a national workshop on Risk Assessment targeting government officials.

Appendix A

Crop	Trait Category	Event/ Applicant	Trait Description	Status
Soybean	Herbicide Tolerant	M-SOY 7878 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerant	M-SOY 8080 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerant	AW 5581 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	AW 7110 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	A6019RG NIDERA	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	A 8000RG NIDERA	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	A 8100RG NIDERA	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 212RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 213RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 214RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 219RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Maize	Herbicide Tolerance	NK 603 Monsanto	Gliphosate Herbicide Tolerant	Research
Maize	Insect Resistant	MON 810 Monsanto	Resistant EuropeanCorn Borer	Research
Maize	Herbicide Tolerance Insect Resistance	MON 810 x NK603	Gliphosate Herbicide Tolerant Resistant European Corn Borer	Research
Cotton	Herbicide Tolerant	RR Monsanto		Research
Cotton	Insect resistance	BT Monsanto		Approved for experimentation
Cotton	Insect resistance and Herbicide tolerant	BTRR Monsanto		Research

Appendix B

Procedure to get government authorization for activities with GMOs applicable to events developed in Paraguay or to be introduced from another country.

Provide to Biosecurity Commission:

- Full name, citizenship, legal address, contact information of applicant
- Name and identity of the GMO
- Projected use of the GMO.
- Detailed agenda of the activities that will be developed
- Amount or volume of GMO that will be used
- Report of the known and available risk analysis
- Suggested method of manipulation, storage, transportation, packaging, labeling and disposal procedures that may be needed in case of emergency.
- A formal declaration stating that all data provided is accurate.

Once the applicant has complied with this request, the Commission will evaluate the necessity to perform the risk analysis evaluation. The Commission may decide whether there is need for the risk analysis evaluation, taking into account the approval that other countries have given to that GMO under similar conditions.

As soon as the Commission reaches a decision, it will be published for three consecutive days in national newspapers. The information published includes name of GMO, name of applicant and requested use, as well as a summary of the risk analysis. After this, and if the GMO under consideration is approved, the public in general has the opportunity to comment on the GMO approval for thirty days. In such a case, the applicant will be contacted and will have 15 days to respond to the opposition. If necessary, the GMO will be placed on a probation for a period that will be decided by the ministries involved, after which the final decision will be made.

Failure to comply with all conditions of a granted authorization may lead to cancellation of the permit, and to legal actions.

All ministries involved in the final decision must be in agreement with the approval.

VI. Reference Materials

Paraguayan Ministry of Agriculture and Livestock (in Spanish)

<http://www.mag.gov.py/>

National Service of Plant Health Quality, SENAVE (in Spanish)

<http://www.senave.gov.py/>